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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,392	12/20/2001	John N. Feder	D0085 NP	4896

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EXAMINER	
KAPUST, RACHEL B	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,392	FEDER ET AL.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8, 9, and 15-19, drawn to isolated nucleic acid molecules comprising either SEQ ID NO: 1 or 34, variants thereof, recombinant vectors, and host cells, classified in class 536, subclass 23.1 and class 435, subclass 320.1.

II. Claims 5-6, 10, and 20, drawn to isolated polypeptides comprising either SEQ ID NO: 2 or 35 and variants thereof, classified in class 530, subclass 350.

III. Claim 7, drawn to isolated antibodies, classified in class 530, subclass 387.1.

IV. Claims 11 and 21-23, drawn to a method for preventing, treating or ameliorating a medical condition by administering a polypeptide comprising either SEQ ID NO: 2 or 35, classified in class 514, subclass 2.

V. Claims 11 and 21-23, drawn to a method for preventing, treating or ameliorating a medical condition by administering a polynucleotide comprising either SEQ ID NO: 1 or 34, classified in class 514, subclass 44.

VI. Claim 12, drawn to a method of diagnosing a pathological condition by determining the presence or absence of a mutation in a polynucleotide, classified in class 435, subclass 6.

VII. Claim 13, drawn to a method of diagnosing a pathological condition by determining the presence or amount of polypeptide expression, classified in class 435, subclass 7.1.

VIII. Claim 14, drawn to a process for making polynucleotide sequences encoding a gene product having altered leucine-rich repeat protein activity, classified in class 435, subclass 91.5.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, and III are not related. The polynucleotides of Group I are composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. The polypeptides of Group II are composed of amino acids linked in peptide bonds that are arranged

spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domains). The antibodies of Group III are also composed of amino acids linked in peptide bonds, however they are arranged spatially in very specific tertiary structures that allow the antibodies to specifically bind to particular regions, *i.e.* epitopes, of the encoded polypeptides. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer.

Group I is not related to Groups IV and VII. The polynucleotides of Group I cannot be used in the methods of Groups IV and VII. Group I and Groups V, VI, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Group I can be used in a variety of methods such as purification assays, ligand binding assays, or other diagnostic assays.

Group II is related to Groups IV and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Group II can be used in a variety of methods such as purification assays, ligand binding assays, or other diagnostic assays. Group II is not related to Groups V, VI, and VIII. The polypeptides of Group II cannot be used in the methods of Groups V, VI, and VIII.

Group III is not related to Groups IV-VIII. The antibodies of Group III cannot be used in the methods of Groups IV-VIII.

Group IV is distinct from Group VII because the methods are drawn to different conditions, they have different method steps, and have different goals and different outcome measures. Group IV is not related to Groups V, VI, and VIII. The methods require different reagents and different method steps.

Group V is distinct from Groups VI and VIII. The methods are drawn to different conditions, they have different method steps, and they have different goals and different outcome measures. Group V is not related to Group VII. The methods require different reagents and different method steps.

Group VI is not related to Group VII. The methods require different reagents and different method steps. Group VI is distinct from Group VIII. The methods are drawn to different conditions, they have different method steps, and they have different goals and different outcome measures.

Group VII is not related to Group VIII. The methods require different reagents and different method steps.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct and/or unrelated for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the searches required for the different groups are different from each other, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK
1/27/04

JANET ANDRES
PATENT EXAMINER